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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,842	12/10/2001	Reena Rao	11378.36US01	1838

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,842	RAO ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-19* is/are pending in the application.

4a) Of the above claim(s) *11-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 4, 2004 has been entered.

This application claims foreign priority PCT/IN01/00182 filed 12/18/2001 under 35 U.S.C. 119(a)-(d). The copy of certified copy of the priority has been filed with the instant Application.

This Office Action is a response to Applicant's request for continued examination (RCE) filed August 4, 2004, and amendment and response to the Final Office Action (mailed February 4, 2004), filed August 4, 2004 wherein claims 1-9 have been amended; claim 10 is cancelled previously.

Currently, claims 1-9 and 11-19 are pending in this application.

It is noted that claims 11-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, of record in the previous Office Action dated February 4, 2004.

Claims 1-9 are examined on the merits herein.

Applicant's amendment limiting the instant claims to "An interesterified coconut oil" and Applicant's remarks that Kaimal et al. does not disclose the specific amount of omega-6 polyunsaturated fatty acids as the instant claimed in claim 1, filed August 4, 2004 with respect to the rejection of claims 1-9 made under 35 U.S.C. 102(b) as being anticipated by Kaimal et al. of record stated in the Office Action dated February 4, 2004 have been considered and are found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to amended claims herein has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "at least 45.5 mol% of omega-6 polyunsaturated fatty acids". First, the specification as originally filed fails to disclose 45.5 **mol**% whereas the specification merely discloses "45.5%" absent any unit (see

page 9 line 10 of the specification). Thus, it is unclear as to whether is by weight percent or by mol percent.

Secondly, the recitation,"at least 45.5 mol%", reads literally on any amounts greater than 45.5 mol%, **without upper limit**. Most importantly, the original specification merely discloses the single point, "46 mol%" as the specific amount of linoleic acid (18:2), the particular omega-6 polyunsaturated fatty acid, in the Table at page 9. Therefore, the original specification fails to disclose any amount greater than 45.5 mol%. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), regarding a corresponding new claim limitation with no upper limit. See also Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000).

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, for **scope** of enablement because the specification, while being enabling for treating, increasing or reducing eicosanoid production in immune compromised patient by administering the

interesterified coconut oil, does not reasonably provide enablement for increasing and reducing eicosanoid production in immune compromised patient by administering the very same composition, since the skilled artisan would view that the recitation, "**modulate**" would reasonably encompass both increasing, and reducing the eicosanoid production, in both opposite directions.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The instant invention pertains to interesterified coconut oil composition to modulate the eicosanoid production in immune compromised patient, i.e., encompassing both increasing and decreasing the eicosanoid production in the patient by administering the very same composition.

The state of the prior art: The skilled artisan would view that modulating the eicosanoid production in immune compromised patient, including increasing and decreasing the eicosanoid production by administering the very same composition, is highly unlikely.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or lack thereof in the art: The skilled artisan would view that, modulating the eicosanoid production in immune compromised patient, including increasing and decreasing the eicosanoid production by administering the very same composition, is highly unpredictable since the skilled artisan would not understand how the same composition or agent could increase and decrease the eicosanoid production at the same time.

The presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to modulate the eicosanoid production in immune compromised patient, including increasing and decreasing the eicosanoid production by administering the very same composition. Applicant's specification provides the experimental results merely showing *lowering the lipid levels in the serum and liver* (see page 11 of the specification).

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in ***undue experimentation*** to achieve methods of modulating the eicosanoid production in immune compromised patient, including increasing and decreasing the eicosanoid production by administering the very same composition, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Kaimal et al. ("Modification of vegetable oils by lipase catalyzed interesterification," Journal of Oil Technologist 's Association of India, Jan-March 2-10, 1989, of record).

Kaimal et al. discloses the interesterification of coconut oil with safflower oil, by the catalyst, lipase, producing the interesterified coconut oil comprising linoleic acid (18:2), a known omega 6 polyunsaturated fatty acid, and lauric acid (12:0). Kaimal et al. also discloses that by interesterification of coconut oil with safflower, linoleic acid has been increased to 8.2% by weight in the interesterified coconut oil from 1.9% by weight in original coconut oil (see Tables 17-18 for example); lauric acid (12:0) has been reduced to 39.7% by weight in the interesterified coconut oil from 47.7% by weight in original coconut oil. Kaimal et al. further discloses that increasing the linoleic acid content in the coconut oil would yield a product of high stability and good nutritive value and good for patients under coronary care (see page 8).

The cited prior art does not expressly disclose the amount of linoleic acid (18:2), a known omega 6 polyunsaturated fatty acid in 45.5 mol% and lauric acid (12:0) in 17 mol%.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare the interesterified coconut oil comprising linoleic acid (18:2), a known omega 6 polyunsaturated fatty acid in 45.5 mol% and lauric acid (12:0) in 17 mol%.

One having ordinary skill in the art at the time the invention was made would have been motivated to prepare the interesterified coconut oil comprising linoleic acid (18:2), a known omega 6 polyunsaturated fatty acid in 45.5 mol% and lauric acid (12:0) in 17 mol%, since the same method, lipase-interesterification of coconut oil with safflower, is known in the art according Kaimal et al. It is also known that linoleic acid has been increased to 8.2% by weight in the interesterified coconut oil from 1.9% by weight in original coconut oil, and lauric acid (12:0) has been reduced to 39.7% by weight in the interesterified coconut oil from 47.7% by weight in original coconut oil according Kaimal et al.

Moreover, the benefit for increasing the linoleic acid content in the coconut oil would be yielding a product of high stability and good nutritive value and good for patients under coronary care according to Kaimal et al. Thus, the teachings of Kaimal et al. has provided the motivation for the instant claimed invention.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Note that it has been well settled that recitation of an inherent property of a composition, e.g., the melting point, as discussed in the previous Office Action.

Applicant is further requested to note that it is well settled that "intended use" of a composition or product, e.g., "hypocholesterolemic and hypotriglyceridemic" in claims 2-4, will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Furthermore, it is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). The product-by-process claim was rejected because the end product. See MPEP 2113.

Thus, even though product-by-process claims herein are limited by and defined by the process, the determination of patentability is based on the product itself. Since the end product, the structured lipids, is known in the art, the product-by-process claim was rejected because the end product.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner, AU 1617
October 21, 2004